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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,665	02/23/2004	Timothy A. Ringeisen	KN P 0142	2680

42016 7590 08/15/2008
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EXAMINER	
AZPURU, CARLOS A	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
08/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,665	RINGEISEN ET AL.	
	Examiner	Art Unit	
	Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *12-68 and 71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 69, 70 and 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the amendment filed 04/28/2008.

The claim objections and double patenting rejection are hereby withdrawn in view of applicant's response. The rejection under 35 USC 102(e) over WO 98/35653 (WO'653) is withdrawn in view of applicant's amendment.

The following rejections are maintained in this action:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-11 and 69 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Delmotte (US Patent No. 6,599,515).

Delmotte disclose mixing the dry gel material with fluid (see Abstract; col 15, lines 25-32). Filler material is added in the form of calcium containing bone-like material at col. 5, line 60-64. Bioactives are added at col. 5, lines 11-27. While fibrin is the preferred gel material, other natural polymers are listed at col. lines 32-39.Synthetic

polymers are included at col. 10 line 40 in the form of copolymers, and in col. 11, lines 33-35 as "recombinant material". It is noted that applicant claims a composition but includes method steps such as solvating and addition of pressure. These are conisdered intended steps and are do not lend patentable weight. Further, if applicant is claiming a product by process, the claims should be reworded as such. Even so, the end product would have to be distinguished by comparative data from the end product as set out by Delmotte. The instant claims are anticipated by Delmotte.

Claims 69 and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 98/35653 (WO'653).

WO'563 sets out a collagen gel produced by the addition of water to collagen (see (Abstract). Bioactives are listed at page 2, lines 31-35. As above the method steps do not differentiate form the gel as disclosed by WO'563. Further, the amount of fluid is clearly greater than than 10% (the maximum amount of collagen). The instant claims are anticipated.

Claim Rejections - 35 USC § 103

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delmotte (US Patent No. 7,135, 027).

Delmotte disclose mixing fibrin (a natural polymer)with water under pressure of a syringe at col. 3, lines 11-12. Filler is added at col. 3, lin 62. Bioactives are also included at col. 6, lines 60-67. Synthetic polymers are incorporated by reference at col. 6, line 28 through US Patent No, 6,066,325 (see col. 7, lines 19-24). Those of ordinary skil would have therefore expected similar therpeutic characteristics form the instantly claimed gel given the gel as taught by Delmotte. There are no unusual and/or unexpected results which would rebut primar facie obviousness. As such, the instantly claimed gel composition would have been obvious to one of ordinary skill at the time of invention given the teachings of Delmotte.

Response to Arguments

Applicant's arguments filed 04/28/2008 have been fully considered but they are not persuasive.

Applicant argues that the Delmotte (Us Patent No. 6,599,515) "does not expressly or implicitly disclose the implantable gel claimed in the independent claims of the instant application. However, as pointed out in the previous action, Delmotte hydrates fibrin (a protein), then applies pressure to it (see Abstract for example). A hydrated protein such a fibrin is art recognized as forming a gel and therefore the teaching is implicit. Hydrogels of this composition are also set out at col. 12, lines 37-63. Such gels are well know for us in bone healing compositions, and accounts for their ability to be applied via syringe. Gels are considered solutions. Lyophilization is specifically recited after placing the solution in a mold (see Col. 12, lines 5-9). Applicant attempts to further distinguish the instant claims by focusing on the porous structure of the gel. However, even the instant claims make reference to the “large surface area biomaterial". Clearly, this added surface area is encompassed by a porous structure. Further, the additional application of force after hydrating is set out in the Abstract and lines 37-50. Further, the reference clearly teaches an implantable gel which is both dehydrated and rehydrated. The instant claims are anticipated by Delmotte. As noted in the prior action, even if the process of making is distinguished, comparative data must be provided to show that the products are actually patentably distinct.

With regard to the rejection under 35 USC 103(a) over Delmotte (US Patent No 7,135,027), applicant traverses, but never sets out how Delmotte differs. If applicant is attempting to differentiate simply by the existence of other ingredients such as calcium based components, it must be pointed out that the instant claims are open ended in

their use of the word “comprising”, and do not exclude these components. The arguments never differentiate why the mixing of fibrin with water under pressure does not read on the claims. Delmotte refers to lyophilized concentrates which must be reconstituted at col. 5, lines 19-25. Therefore it is still deemed that the claims would have been obvious to one of ordinary skill at the time of invention given the teachings of Delmotte.

The following are new rejections of the claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 69 and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 98/35653 (WO'653).

WO'563 sets out a collagen gel produced by the addition of water to collagen (see (Abstract). Bioactives are listed at page 2, lines 31-35. As above the method steps do not differentiate form the gel as disclosed by WO'563. Further, the amount of fluid is clearly greater than 10% (the maximum amount of collagen). The instant claims are anticipated.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, and 70 and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. ***

Support could not be found for the invention as claimed in the original specification. Specifically, references to "lyophilization", "high surface area bioactive", "adding less fluid than was removed during lyophilization", "at least about 3.3 percent

(w/v) of said fluid", and "coating said large surface area of said biomaterial with said fluid", could not be found. The claims are considered to contain new matter.

It is noted that claim 71 belongs with the non –elected invention and depends upon non-elected claim 61.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Election/Restrictions

This application contains claims 12-68 and 71 drawn to an invention nonelected with traverse in the reply filed on 09/27/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/ Carlos A. Azpuru

Primary Examiner, Art Unit 1615

Primary Examiner
Art Unit 1615

caz